REMARKS

The Final Office Action mailed October 12, 2006, has been received and reviewed. Claims 17 through 21, 23 through 27, 29 through 31, 33 through 41, and 49 through 53 are currently pending in the application. Claims 17 through 21, 23 through 27, 29 through 31, 33 through 41, and 49 through 53 stand rejected. Applicants propose to amend claims 17, 18, 33, and 36, and respectfully request reconsideration of the application as proposed to be amended herein.

35 U.S.C. § 112 Claim Rejections

Claims 17 through 21, 23 through 31, 33 through 41, and 49 through 53 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 17 through 21, 23 through 31, 33 through 41, and 49 through 53 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse this rejection, as hereinafter set forth.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 5,882,676 to Lee et al. in view of U.S. Patent No. 5,668,170 to Gyory

Claims 17 through 21, 23 through 27, 30, 31, 33 through 36, 38, 40, 41, and 49 through 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,882,676) in view of Gyory (U.S. Patent No. 5,668,170). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

> art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The 35 U.S.C. § 103(a) obviousness rejections of claims 17 through 21, 23 through 27, 30, 31, 33 through 36, 38, 40, 41, and 49 through 53 are improper because Lee et al. in combination with Gyory do not teach all of the claim limitations and, in fact, teach away from the claimed invention.

Independent claims 17, 33 and 36 are drawn to implantable or injectable compositions including a sterile beneficial agent and a sterile, non-aqueous, single-phase biocompatible vehicle comprising a solvent, a surfactant, and a polymer, wherein the solvent is lauryl lactate and the solvent, the surfactant, and the polymer are selected and formulated such that the non-aqueous, single-phase biocompatible vehicle exhibits a viscosity capable of suspending the at least one beneficial agent.

Lee et al. teaches transdermal administration of a drug together with an acyl lactylate permeation enhancer to permit topical administration of a drug through the skin. As disclosed in Lee et al., many drugs have low permeability through intact skin and cannot be delivered in therapeutically effective amounts. Use of a permeation enhancer increases skin permeability so that drugs can be delivered in therapeutically effective amounts. The permeation enhancers are specifically used to be applied to skin surfaces and, because of their intended mode of application, are not sterile.

Gyory likewise discloses compositions that are delivered through the skin surface, but uses electrotransport enhancers to permeate through the body surface and transport the beneficial agent through the skin. The compositions of Gyory are likewise specifically used to be applied to skin surfaces and, because of their intended mode of application, are not sterile.

Neither Lee et al. or Gyory, alone or in combination, teach or suggest an implantable or injectable compositions that includes a sterile beneficial agent and a sterile, non-aqueous, single-

phase biocompatible vehicle. In fact, not only do Lee et al. and Gyory fail to teach all of the claim limitations, these references teach away from the sterile implantable or injectable compositions of the present invention since they are expressly drawn to topical formulations that can only be used to enhance topical delivery of agents and are not intended to be used via direct injection or implantation into the body.

In view of the claim amendments and the argument herein, Applicants respectfully request withdrawal of the present rejection.

Obviousness Rejection Based on U.S. Patent No. 5,882,676 to Lee et al. in view of U.S. Patent No. 5,668,170 to Gyory and further in view of U.S. Patent No. 4,078,060 to Benson et al.

Claims 17, 29, 37 and 39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,882,676) in view of Gyory (U.S. Patent No. 5,668,170) and further in view of Benson et al. (U.S. Patent No. 4,078,060). Applicants respectfully traverse this rejection, as hereinafter set forth.

The 35 U.S.C. § 103(a) obviousness rejections of claims 17, 29, 37 and 39 are improper because Lee et al. in combination with Gyory and Benson et al. do not teach all of the claim limitations and, in fact, teach away from the claimed invention. Additionally, there is no suggestion or motivation to combine Benson et al. with Lee et al. and Gyory.

As previously discussed, Lee et al. and Gyory, in combination, fail to teach all of the claim limitations and, in fact, teach away from the claimed invention.

Benson et al. is relied upon as teaching that testosterone can be administered parenterally with an antioxidant. However, Benson et al. does not overcome the deficiencies of Lee et al. and Gyory, nor does it overcome the fact that Lee et al. and Gyory teach away from the present invention. Additionally, because Benson et al. is drawn to parenteral administration of testosterone with an antioxidant, there is no suggestion or motivation to combine the references since the former (Lee and Gyory) are drawn to topical administration of agents and the latter (Benson) is drawn to parenteral administration of agents with antioxidants, particularly in view of the amendments to the claims requiring that the beneficial agent and the non-aqueous, single-phase biocompatible vehicle (or alternatively, the injectable or implantable formulations as a

whole) be sterile.

In view of the claim amendments and the argument herein, Applicants respectfully request withdrawal of the present rejection.

ENTRY OF AMENDMENTS

The proposed amendments to claims 17, 18, 33, and 36 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested upon filing of a Notice of Appeal herein.

CONCLUSION

Claims 17-21, 23-27, 29-31, 33-41, and 49-53 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,

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